

PHILIP R. SELLINGER  
United States Attorney  
SUSAN PAPPY  
Assistant United States Attorney  
970 Broad Street, Suite 700  
Newark, NJ 07102  
Tel.: 201-407-2971  
e-mail: [susan.pappy@usdoj.gov](mailto:susan.pappy@usdoj.gov)

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA et al.,	)	
<i>ex rel.</i> JESSICA PENELOW AND CHRISTINE	)	Hon. Zahid N. Quraishi
BRANCACCIO,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. 12-7758 (ZNQ)
v.	)	
	)	<b>STATEMENT OF INTEREST</b>
JOHNSON & JOHNSON, JANSSEN	)	<b>RE: DEFENDANT’S MOTION</b>
PRODUCTS, LP,	)	<b>FOR JUDGMENT AS A</b>
	)	<b>MATTER OF LAW</b>
Defendants.	)	
	)	

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The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, is the federal government’s primary tool to combat fraud and recover losses due to fraud in federal programs. Accordingly, the United States has a substantial interest in the proper interpretation of the FCA. The United States also administers the Medicare and Medicaid programs, and therefore has a substantial interest in the proper interpretation of the statutes, regulations, and guidance that govern those programs. The United States submits this Statement of Interest to address arguments that Janssen made in its Motion for Judgment as a Matter of Law (“Motion”) relating to the application of the FCA’s public disclosure bar and the constitutionality of the FCA’s *qui tam* provisions.

The United States notes that it previously submitted a statement of interest to address arguments that Janssen made in its Motion to Dismiss. ECF 75. Specifically, the United States

explained that drugs prescribed for indications approved by the Food and Drug Administration (FDA) are not per se “reasonable and necessary” for purposes of Medicare and Medicaid reimbursement and that false statements that induce a physician to prescribe a particular drug can be actionable under the FCA even if the drug is prescribed for an FDA-approved indication. The United States incorporates those arguments by reference into this Statement of Interest.

The United States takes no position on the other arguments raised by Defendants in their Motion for Judgment as a Matter of Law.

**I. The United States Opposes Dismissal of Certain Claims Based on the Public Disclosure Bar.**

In its Motion, Janssen argues that Judgment as a Matter of Law is appropriate because, *inter alia*, this Court has no subject matter jurisdiction under the FCA’s public disclosure bar. Motion at 52-53. Specifically, Janssen contends that Relators’ allegations in this case were publicly disclosed in connection with two Corporate Integrity Agreements that Janssen executed with the Department of Health and Human Services Office of Inspector General in 2010 and 2013.

The False Claims Act states in pertinent part:

The court shall dismiss an action or claim under this section, ***unless opposed by the Government***, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed – (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis added). Thus, if the United States objects, the Court may not dismiss the action on the ground of public disclosure.

Pursuant to the FCA, 31 U.S.C. § 3730(e)(4)(A), the United States hereby exercises its right to object to dismissal of Relators' Amended Complaint on the basis of the public disclosure bar for FCA claims accruing on or after March 23, 2010.<sup>1</sup> Accordingly, Defendants' motion to for judgment as a matter of law on the ground of the public disclosure bar should be denied for those claims. The United States takes no position on the application of the FCA's pre-amendment public disclosure bar to FCA claims in this action accruing prior to March 23, 2010.

## **II. The FCA's *Qui Tam* Provisions are Constitutional.**

In the last two pages of its Motion, Janssen asks this Court to hold that the *qui tam* provisions of the FCA are unconstitutional. Motion at 54-55. Janssen argues that Relators' prosecution of this declined *qui tam* case represents an impermissible delegation of Executive power to a private party. But courts consistently have rejected such arguments, recognizing that the FCA's *qui tam* provisions are consistent with the constitutional structure. *See United States ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787 (10th Cir. 2002); *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001) (en banc); *United States ex rel. Taxpayers Against Fraud v. General Elec. Co.*, 41 F.3d 1032 (6th Cir. 1994); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743 (9th Cir. 1993); *see also United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148 (2d Cir. 1993). This Court should hold likewise.

When Congress enacted the FCA in 1863, it included *qui tam* provisions, following a "long tradition of [such] actions in England and the American Colonies." *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 774 (2000). These provisions allow

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<sup>1</sup> The FCA's public disclosure bar was amended on March 23, 2010. In *Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010), the Supreme Court held that this amendment was not retroactive. Thus, it applies only to FCA claims accruing on or after the effective date of the amendment.

private individuals, known as relators, to bring suit “for the person and for the United States Government” against “[a]ny person” who defrauds the government. *Id.* at 769 (quoting 31 U.S.C. §§ 3729(a), 3730(b)(1)). If the suit is successful, the relator is entitled to a share of the recovery. *Id.* at 769-70. The FCA has become “the government’s ‘primary litigative tool for combatting fraud,’” with the FCA’s *qui tam* provisions serving “as a critical supplement to government enforcement.” *United States ex rel. Doe v. Staples, Inc.*, 773 F.3d 83, 84 (D.C. Cir. 2014) (quoting S. Rep. No. 99-345, at 2, 4 (1986)).

At its core, the separation of powers doctrine focuses on “the allocation of official power among the three coequal branches of our Government.” *See Clinton v. Jones*, 520 U.S. 681, 699 (1997). “[I]n determining whether [legislation] disrupts the proper balance between the coordinate branches, the proper inquiry focuses on the extent to which it prevents the Executive Branch from accomplishing its constitutionally assigned functions.” *Nixon v. Administrator of Gen. Servs.*, 433 U.S. 425, 443 (1977). Courts repeatedly have held that *qui tam* actions do not upset such a balance.

*Qui tam* relators are private litigants. The Supreme Court has expressly declined to adopt a theory that they sue as “agent[s] of the United States.” *Stevens*, 529 U.S. at 772. Their Article III standing exists due to a “concrete *private* interest in the outcome of the suit” that arises from Congress’s “partial assignment of the Government’s damages claim” to them. *Id.* at 772-73 (alteration accepted and emphasis added). While relators bring *qui tam* actions “in the name of the Government,” 31 U.S.C. § 3730(b)(1), this is a procedural practice that does not alter their status as private litigants with private interests. *See Stevens*, 529 U.S. at 780-81 n.9, 786 n.17 (actions pursued by relators are “private suit[s]” brought by “private parties.”). Relators are not transformed into “official[s] of the United States” merely because, in pursuit of their own

interests, they further a federal interest in remedying and deterring fraud on the United States.

*See Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1514 (2019)

(“§ 3731(b)(2)’s use of the definite article ‘the’ suggests that Congress did not intend for any and all private relators to be considered ‘the official of the United States.’”).

The deep historical roots of *qui tam* provisions confirm that the FCA does not violate the separation of powers. “Statutes providing for actions by a common informer, who himself had no interest whatever in the controversy other than that given by statute, have been in existence for hundreds of years in England, and in this country ever since the foundation of our government.” *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 541 n.4 (1943). In *Stevens*, the Supreme Court reviewed this “long tradition of *qui tam* actions in England and the American Colonies,” as well as the “considerable number” of statutes with *qui tam* provisions passed by the First Congress. *See Stevens*, 529 U.S. at 774-77. The Court found this evidence “well nigh conclusive” in establishing that *qui tam* relators have Article III standing. *Id.* at 777.

The historical evidence is also highly relevant to the constitutional question presented here. *See Riley*, 252 F.3d at 752 (finding it “logically inescapable that the same history that was conclusive on the Article III question in *Stevens* with respect to *qui tam* lawsuits initiated under the FCA is similarly conclusive with respect to the Article II question concerning this statute”). The First Congress enacted numerous *qui tam* provisions, thus making clear that the Framers did not believe relators were performing functions that only federal officers could properly perform. *See Bowsher v. Synar*, 478 U.S. 714, 723-24 (1986) (acts of the First Congress “provide[] contemporaneous and weighty evidence of the Constitution’s meaning since many of the Members of the First Congress had taken part in framing that instrument”) (quotation marks omitted). And the long tradition of *qui tam* actions in the United States after the Framing

provides “additional evidence that the doctrine of separated powers does not prohibit” this unique practice, given that “‘traditional ways of conducting government . . . give meaning’ to the Constitution.” *Mistretta v. United States*, 488 U.S. 361, 401 (1989) (quoting *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 610 (1952) (Frankfurter, J., concurring)); *see also NLRB v. Noel Canning*, 134 S. Ct. 2550, 2559-60 (2014).

Courts rejecting constitutional challenges to the FCA have also observed that the United States retains significant control over *qui tam* suits, *see Riley*, 252 F.3d at 753-57; *Taxpayers Against Fraud*, 41 F.3d at 1041; *Kelly*, 9 F.3d at 753-55; *Kreindler & Kreindler*, 985 F.2d at 1155, a point that the Supreme Court also recently underscored. *See United States ex rel. Polansky v. Exec. Health Res., Inc.*, 143 S. Ct. 1720, 1729 n.2, 1734 (2023). If the government intervenes in a *qui tam* suit, “the relator loses control” and the action is “‘conducted by the Government.’” *Id.* at 1728 (quoting 31 U.S.C. § 3730(b)(4)(A)). And even where the government initially declines to intervene, the Supreme Court confirmed in *Polansky* that it may intervene at a later time and move to dismiss the relator’s claims. *Id.* at 1732, 1734. Such motions are subject to highly deferential review under Federal Rule of Civil Procedure 41(a); indeed, the Supreme Court emphasized that district courts must grant dismissal “in all but the most exceptional cases”—“even if the relator presents a credible assessment to the contrary,” *Polansky*, 143 S. Ct. at 1734.

Beyond the government’s broad dismissal authority, the FCA also provides the Executive with an array of tools for protecting the government’s interests in cases where it does not intervene. The government can “elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty.” 31 U.S.C. § 3730(c)(5). It can settle a *qui tam* action over the relator’s objection. *See id.*

§ 3730(c)(2)(B). If it instead permits the *qui tam* action to proceed, the government is entitled to, among other things: (1) receive copies of all pleadings and deposition transcripts; (2) move to stay any discovery by the relator that “would interfere with the Government’s investigation or prosecution of a criminal or civil matter arising out of the same facts”; and (3) prevent the relator from dismissing or settling a case without the government’s approval. § 3730(b)(1), (c)(3), (4). And because the first-to-file bar and the public disclosure bar do not apply to the government, the government can bring its own action even after a relator’s suit is dismissed, subject to principles of claim preclusion. *See* 31 U.S.C. § 3730(b)(5), (e)(4). Courts rejecting separation-of-powers concerns to the *qui tam* provisions have noted all these mechanisms of “executive control.” *Kelly*, 9 F.3d at 750-55; *see also, e.g., Riley*, 252 F.3d at 753; *Taxpayers Against Fraud*, 41 F.3d at 1041.

The recent decision of a single district court in *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, 2024 WL 4349242 (M.D. Fla. Sept. 30, 2024), provides no sound basis to depart from the longstanding consensus among the courts of appeals. The district court based its analysis on the premise that, when relators bring FCA suits, they are suing on behalf of the United States in the exercise of “core executive power.” *Id.* at \*8. But as described above, *qui tam* suits are private claims, pursuing the relator’s interest in a share of the recovery as partially assigned by the government. The *Zafirov* court further erred in concluding that relators occupy an “office” akin to that of the Attorney General, which may vary from occupant to occupant. 2024 WL 4349242, at \*11. Whereas only one person holds the office of Attorney General at any given time, there are many relators, and a statute empowering an indeterminate number of private citizens to exercise certain powers does not create an “office.” This error of the district court is further underscored by the fact that when a relator dies, his estate may be substituted in

his place, *id.* at \*14, which is obviously not true for an “office” in the United States government. Finally, even while acknowledging that “early Congresses enacted at least some statutes containing an enforcement mechanism roughly analogous to the FCA.” *id.* at \*17, the court improperly discounted the weight of this Founding-era evidence and also failed to square it with the Supreme Court’s reliance on those early statutes in *Stevens*.

For these reasons, the FCA’s *qui tam* provisions are consistent with the Constitution’s separation of powers. Accordingly, if the Court reaches the defendant’s constitutional arguments, it should reject them, as every federal Circuit Court to decide the issue has done.

Respectfully submitted,

BRIAN BOYNTON  
Principal Deputy Assistant  
Attorney General

PHILIP R. SELLINGER  
United States Attorney

/s/ Susan Pappy

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SUSAN PAPPY  
Assistant United States Attorney  
970 Broad Street, Suite 700  
Newark, NJ 07102  
Tel.: 201-407-2971  
e-mail: [susan.pappy@usdoj.gov](mailto:susan.pappy@usdoj.gov)

JAMIE A. YAVELBERG  
EDWARD C. CROOKE  
Civil Division  
Commercial Litigation Branch  
P.O. Box 261  
Ben Franklin Station  
Washington, D.C. 20044  
(202) 353-0426